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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/282,679 03/31/99 FALO

L 214001-00703

003705 HM22/0825  
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EXAMINER

VANDER VEGET, F

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

08/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/282,679

Applicant(s)  
Falo et al

Examiner  
F. Pierre VanderVegt

Group Art Unit  
1644



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-36 ~~is~~/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-36 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

This application is a continuation-in-part of application S.N. 09/030,985, which claims priority to provisional application 60/039,472.

Claims 1-36 are currently pending in this application.

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**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to  
10 this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written  
15 Restrictions.

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- 20 I. Claims 1-13, drawn to a method of generating antigen-specific T cells, classified in class 435, subclass 373.
- II. Claims 14-19, drawn to an antigen-specific T cell, classified in class 435, subclass 325.
- 25 III. Claims 20-27, drawn to a method of effecting immunotherapy in a host, classified in class 424, subclass 93.71.
- IV. Claims 28-31, drawn to a method of identifying antigens by loading antigen presenting cells with tumor-derived peptides, classified in class 435, subclass 7.1.
- 30 V. Claims 32-35, drawn to a method of identifying antigens using DNA or cDNA transfected target cells, classified in class 435, subclass 6.

VI. Claim 36, drawn to a method of generating an animal model, classified in class 424, subclass 93.71.

2. The inventions are distinct, each from the other because of the following reasons:

5 Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the activated T cells of Group II are claimed as a product-by-process, however given the broadest  
10 reasonable interpretation of the claims, Group II is simply drawn to antigen-specific T cells obtainable by any method, as the instant method does not result in T cells which are obtainable by other methods, such as isolation of antigen-specific T cells from peripheral blood or from lymph nodes.

15 Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related because, although they are a method of making and using antigen-specific T cells, respectively, the method of Group III can be performed using antigen-specific T cells obtained by any manner or source and is not dependent upon the method of making of  
20 Group I.

25 Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to administration of cells for different purposes. Group III is drawn to the treatment of a condition in a subject in need of treatment, while Group VI is drawn to the administration of cells to an animal in order to evaluate in vivo effects for research purposes.

30 Inventions IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods of research of antigen recognition by T cells using methods and

materials which are distinct from one another. Group IV requires the loading of dendritic cells with peptides extracted from tumor cells in order to determine whether those peptides can stimulate T cell activation. Group V requires the transfection of target cells with DNA or cDNA in order to assess destruction of the target cells by activated T cells and elucidating the product of the transfecting nucleic acid. Group VI requires the introduction of activated T cells into tumor-bearing antigens in order to determine whether antigen-specific T cells are effective against a particular tumor type. Accordingly, the methods each requires a different manner of practice and measures a different parameter of an immune response.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Diane Meyers on August 18, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and even-numbered Mondays (on 1999 365-day calender) from 7:00 am to 4:00 pm ET. A message may be left on the Examiner's

voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

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10 F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
August 24, 1999